NOTICE: Issued for public comment purposes only.

This Global Harmonization Task Force working draft results from international negotiations. We are issuing it for public comment in accordance with 21 CFR 10.115, at the same time as other countries so we may review the public comments and resume negotiations in a timely manner.

WORKING DRAFT

Global Harmonization Task Force

Title: Medical Devices Classification

Authoring Group: Study Group 1 of the Global Harmonization Task Force

Date: January 10, 2001

Table of Contents

Preface

This document was produced by the Global Harmonization Task Force, a voluntary consortium of representatives from medical device regulatory authorities and trade associations from around the world. The document is intended to provide non-binding guidance to Regulatory Authorities for use in the regulation of medical devices and has been subject to consultation throughout its development and endorsement by the current Chair. Endorsement by the Chair signifies acceptance by consensus amongst members of the GHTF Steering Committee, as a document to be promoted by all members of the GHTF.

The primary way in which the Global Harmonization Task Force (GHTF) achieves its goals is through the production of harmonized guidance documents suitable for implementation or adoption by member Regulatory Authorities or by nations with developing regulatory programmes.

1.0 Introduction

The purpose of this document is to allow a manufacturer to allocate its medical device to an appropriate risk class using a set of harmonized rules. Subsequently, such classification will prescribe how the manufacturer will demonstrate that its device complies with the *Essential Principles for Safety and Performance of Medical Devices, Labelling for Medical Devices* and any other relevant controls, should it be required or requested so to do by a Regulatory Authority, Conformity Assessment Body, user or third party.

This guidance document has been prepared by Study Group 1 of the Global Harmonization Task Force (GHTF). Comments or questions about it should be directed to either the Chairman or Secretary of GHTF Study Group 1 whose contact details may be found on the GHTF web page.

2.0 Scope

This document applies to all products that fall within the definition of a medical device that appears within the GHTF document *Information Concerning the Definition of the Term "Medical Device"* and to active implantable medical devices. In-vitro diagnostic medical devices are outside the scope of this document.

This document has been developed to encourage and support global convergence of regulatory systems and the means of achievement. It is intended for use by medical devices Regulatory Authorities, Conformity Assessment Bodies and industry, and will provide benefits in establishing, in a consistent way, an economic and effective approach to the control of medical devices in the interest of public health. The document will be of value to countries developing or amending regulations.

Regulatory Authorities that are developing new classification schemes or amending existing ones are encouraged to consider the adoption of this system, as this will help to reduce the diversity of systems world-wide and facilitate the process of harmonization.

The regulatory requirements of some countries may not, at present, reflect the contents of this document. Regulatory Authorities with existing systems are also encouraged to consider adopting this system.

3.0 References

SG1/N009 *Labelling for Medical Devices.*

SG1/N020 *Essential Principles of Safety and Performance of Medical Devices*.

SG1/N029 *Information Concerning the Definition of the Term "Medical Device"*.

4.0 Definitions

Active medical device: Any medical device operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices.

Active therapeutical device: Any active medical device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or handicap.

Active device for diagnosis: Any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.

Central circulatory system: `Central circulatory system' means the major internal blood vessels including the following:
arteria pulmonales, aorta ascendens, arteria coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteria cerebrales, truncus branchicephalicus, venae cordis, venae pulmonales, vena cava superior, vena cava inferior

Central nervous system: `Central nervous system' means brain, meninges and spinal cord.

Duration of use

Transient: Normally intended for continuous use for less than 60 minutes.

Short term: Normally intended for continuous use for not more than 30 days.

Long term: Normally intended for continuous use for more than 30 days.

Invasive devices

Invasive device: A device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.

Body orifice: Any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma.

Surgically invasive device: An invasive device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation.

Devices other than those referred to in the previous subparagraph and which produce penetration other than through an established body orifice, shall be treated as surgically invasive devices.

Implantable device: Any device which is intended:-

- to be totally introduced into the human body or,
- to replace an epithelial surface or the surface of the eye,

by surgical intervention which is intended to remain in place after the procedure.

Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device.

Harm: Physical injury or damage to the health of people.

Hazard: Potential source of harm.

Immediate Danger: A situation where therapy is required as soon as possible after the abnormal condition is diagnosed in order to prevent serious harm to the patient.

Life Supporting: Maintains the life of a patient over a short period of time.

Life Sustaining: Maintains the life of a patient over a long period of time.

Potentially Hazardous Manner: The potential of the device, when used as intended, to harm the patient due, for example, to the lack of direct oversight of the patient by a clinician or the high risk associated with the particular application of the device or the type of technology involved.

Reusable surgical instrument: Instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without

connection to any active medical device and which can be used after appropriate procedures have been carried out.

Risk: Combination of the probability of occurrence of harm and the severity of that harm.

5.0 General Principles

Regulatory controls are intended to safeguard the health and safety of patients, users and other persons by ensuring that manufacturers of medical devices follow specified procedures during design, manufacture and marketing.

The risk presented by a particular device depends substantially on its intended purpose and the effectiveness of the risk management techniques applied during design, manufacture and use.

Regulatory controls should be proportional to the level of risk associated with a medical device. The level of regulatory control should increase with increasing degree of risk, taking account of the benefits offered by use of the device. At the same time, the imposition of regulatory controls should not place an unnecessary burden on regulators or manufacturers.

Therefore:

- there is a need to classify medical devices based on their risk to patients, users and other persons; and
- there is benefit for manufacturers and Regulatory Authorities if a globally harmonized classification system is developed.

6.0 Recommendations

6.1 Primary Recommendations

- Regulatory Authorities should work towards the establishment of a global classification system;
- such a system should be based upon common features of existing national requirements with the aim of future convergence;
- this system should consist of four risk classes. Based on experience of GHTF Founding Members, this is sufficient to accommodate all medical devices and allows an efficient and graduated system of conformity assessment controls;
- the determination of class should be based on a set of rules derived from those features of devices that create risk;
- the set of rules should be sufficiently clear that manufacturers may readily identify the class of their medical devices, subject, when appropriate, to confirmation by the Regulatory Authority;

- the rules should be capable of accommodating future technological developments;
- any exceptions to the classification rules introduced by a Regulatory Authority to reflect and implement national health policy within its own jurisdiction should be minimized and eliminated in the long term.

6.2 Factors Influencing Device Classification

A number of factors, including for example the duration of device contact with the body, the degree of invasiveness, and local *versus* systemic effects may, alone or in combination, affect device classification.

Where a medical device has features that place it into more than one class, conformity assessment should be based on the highest class indicated.

Notwithstanding the risk class of a particular medical device, all devices should conform to the applicable *Essential Principles of Safety and Performance of Medical Devices* and for *Labelling for Medical Devices*.

Each Regulatory Authority may assign names or numbers to the risk classes, based on local preference. At this time, regulatory controls assigned to each Class by different Regulatory Authorities have yet to be harmonized and vary[1].

6.3 Subsequent Reclassification of a Device

The recognized level of risk may change based on post-market experience or technological improvements to the device. This may lead to a need for reclassification. Regulatory Authorities are encouraged to include a process for changing the assigned classification of a device, when necessary and to consult with their international counterparts when considering reclassification of a device.

[1] Guidance on the link between risk class and conformity assessment will be the subject of a future GHTF document.

6.4 Proposed General Classification System for Medical Devices

Figure 1 indicates the four risk classes of devices. The examples given are for illustration only and the manufacturer must apply the classification rules to each medical device according to its intended purpose.

Figure 1: Proposed general classification system for medical devices

CLASS	RISK LEVEL	DEVICE EXAMPLES
A	Low Risk	Simple surgical instruments / tongue depressors
B	Low-moderate Risk	Hypodermic Needles / suction equipment
C	High-moderate Risk	Lung ventilator / orthopaedic implants
D	High Risk	Heart valves / implantable defibrillator

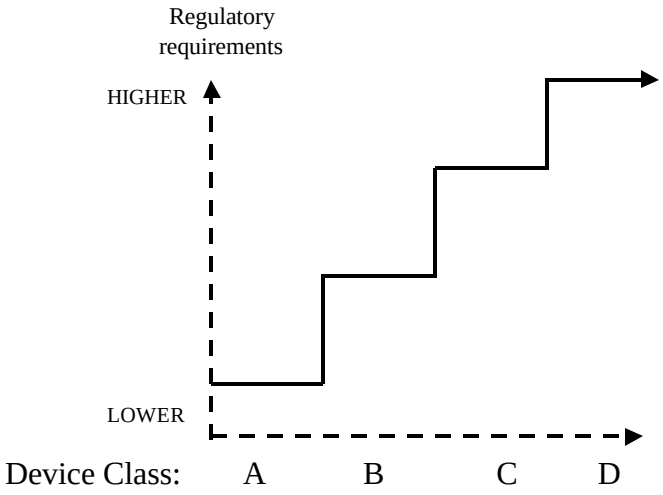
Figure 2 shows a conceptual illustration of increasing levels of regulatory requirements as the device risk class increases. These regulatory controls may include, for example:-

- operation of a quality system (recommended for all devices);
- documentation of clinical evidence to support the manufacturer's claims;
- technical data;
- product testing using in-house or independent resources;
- the need for and frequency of independent external audit of the manufacturer's quality system; and
- independent external review of the manufacturer's technical data.

The concept is expanded in a document entitled *Global Approach to Premarket Conformity Assessment for Medical Devices*[2].

[2] Currently being drafted and not available for comment at this time.

Figure 2: Conceptual illustration of regulatory controls increasing with device risk class



7.0 The Determination of Device Class

The manufacturer should:

1. decide if the product concerned is a medical device, using *Information Document Concerning the Definition of the Term "Medical Device";*

2. determine the intended purpose of the medical device;

3. take into consideration all the rules that follow in order to establish the proper classification for the device, noting that **where a medical device has features that place it into more than one class, conformity assessment should be based on the highest class indicated;** and

4. determine that the device is not subject to special national rules that apply within a particular jurisdiction.

   NOTE: Where special national rules <u>are</u> applied, resulting in a device class other than that suggested by the present rules, then a different conformity assessment procedure may be indicated. This may have an effect on the acceptability of such devices for free movement in the global context unless other or additional, conformity assessment procedures are carried out.

8.0 Classification Rules

RULE	COMMENT
➢ ***NON-INVASIVE DEVICES***	
1. All non-invasive devices are in Class A, unless one of the rules set out hereinafter applies.	These devices either do not touch the patient or contact intact skin only. Non-invasive devices that are indirectly in contact with the body & can influence internal physiological processes by storing, channelling or treating blood, other body liquids or liquids which are returned or infused into the body or by generating energy that is delivered to the body are outside the scope of this rule (see Rule 2).
2. All non-invasive devices intended for channelling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in Class B: - if they may be connected to an active medical device in Class B or a higher class, - if they are intended for use of storing or channelling blood or other body liquids or for storing organs, parts of organs or body tissues, in all other cases they are in Class A.	These are indirectly invasive devices that channel or store liquids that will eventually be delivered into the body (see comment for Rule 1). "Connection" to an active device covers those circumstances where the safety and performance of the active device is influenced by the non-active device and *vice versa*.
3. All non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body are in Class C, unless the treatment consists of filtration, centrifugation or exchanges of gas, heat, in which case they are in Class B. **[NOTE**: there is a proposal that the removal of white blood cells is not by simple filtration and therefore devices used for this purpose remain in Class C – **comment required.]**	These are indirectly invasive devices that treat or modify substances that will eventually delivered into the body (see comment for Rule 1). **NOTE**: for the purpose of this definition, 'modification' does not include filtration or centrifuging. **NOTE:** filtration technology can be used to effect complicated separation steps and devices using such technology are in Class C. These devices are normally used in conjunction with an active device within the scope of either Rule 9 or 11.

4. All non-invasive devices which come into contact with injured skin: - are in Class A if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates, - are in Class C if they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent, - are in Class B in all other cases, including devices principally intended to manage the micro-environment of a wound.	These are devices that make contact with injured skin. Devices of this type where the manufacturer claims that they promote healing through physical methods other than providing a barrier are in Class C. Devices containing medicinal products are within the scope of Rule 13 and are in Class D.
➢ ***INVASIVE DEVICES***	
5. All invasive devices with respect to body orifices, other than surgically invasive devices and which are not intended for connection to an active medical device: - are in Class A if they are intended for transient use, - are in Class B if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which case they are in Class A, - are in Class C if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class B. All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to an active medical device in Class B or a higher class, are in Class B. **[NOTE**: there is a proposal that contact lenses be in Class C – **comment required.]**	These devices are invasive in body orifices. Classification depends on the time of invasion and the sensitivity of the orifice to such invasion. **NOTE**: stomas are considered a body orifice for the purpose of this rule but other surgically invasive devices are within the scope of Rule 6.

6. All surgically invasive devices intended for transient use are in Class B unless they are: - intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class D, - reusable surgical instruments, in which case they are in Class A, - intended to supply energy in the form of ionizing radiation in which case they are in Class C, - intended to have a biological effect or be wholly or mainly absorbed in which case they are in Class C, - intended to administer medicines by means of delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of appli-cation, in which they are in Class C.	These devices are surgically invasive and intended for transient use. Most create a conduit through the skin, or are surgical instruments, or are various types of catheter/sucker etc. **NOTE**: a surgical instrument connected to an active device is in a higher class than A. **NOTE**: a surgical instrument other than those in Class D is in Class B if intended for single use and in Class A if reusable. **NOTE**: the 'biological effect' referred to is an intended one rather than unintentional.
7. All surgically invasive devices intended for short-term use are in Class B unless they are intended: - either specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class D, - or specifically for use in direct contact with the central nervous system, in which case they are in Class D, - or to supply energy in the form or ionizing radiation in which case they are in Class C, - or to have a biological effect or to be wholly or mainly absorbed in which case they are in Class D, - or to undergo chemical change in the body, or to administer medicines, in which case they are in Class C.	These devices are surgically invasive and intended for short-term use. Most are used in the context of surgery or post-operative care, or are infusion devices, or are catheters of various types. NOTE: the term 'administration of medicines' implies storage and/or influencing the rate/volume of medicine delivered not just channelling.

8. All active and non-active implantable devices, and long-term surgically invasive devices, are in Class C unless they are intended: , - to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D, - to be life supporting or life sustaining, in which case they are in Class D, - to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class D, - or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in Class D.	These devices are surgically invasive and intended for long-term use and implantable devices. Active implantable medical devices are in Class D. **NOTE**: hydroxy-apatite is considered as having biological effect only if so claimed and demonstrated by the manufacturer. **NOTE**: bone cement is not within the scope of the term 'chemical change in the body' since any change takes place in the short rather than long term.
➢ ***ACTIVE DEVICES – ADDITIONAL RULES***	
9. All active therapeutic devices intended to administer or exchange energy are in Class B unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are in Class C. All active devices intended to control or monitor the performance of active therapeutic devices in Class C, or intended directly to influence the performance of such devices are in Class C.	These are active therapeutic devices intended to administer or exchange energy. Most are electrically powered equipment used in surgery; some are stimulators. **NOTE**: the term 'potentially hazardous' refers to the type of technology involved and the intended application. This includes devices that use ionizing radiation for their therapeutic effect.
10. Active devices intended for diagnosis are in Class B: - if they are intended to supply energy which will be absorbed by the human body, except for devices used to illuminate the patient's body, in the visible spectrum, - if they are intended to image *in vivo* distribution of radiopharmaceuticals, - if they are intended to allow direct	These are active devices intended for diagnosis. They include equipment for ultrasonic diagnosis/imaging, capture of physiological signals, interventional radiology and diagnostic radiology.

diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of CNS in which case they are in Class C. Active devices intended to emit ionizing radiation and intended for diagnostic and/or interventional radiology including devices which control or monitor such devices, or which directly influence their performance, are in Class C.	
11. All active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body are in Class B, unless this is done in a manner: - that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are in Class C.	These active devices administer and remove medicines and other substances to/from the body. Most are drug delivery systems, or anaesthesia equipment.
12. All other active devices are in Class A.	
➢ ***ADDITIONAL RULES***	
13. All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, and which is liable to act on the human body with action ancillary to that of the devices, are in Class D.	These devices cover combination devices that incorporate medicinal substances in a secondary role.
14. All devices manufactured from or incorporating animal or human cells/tissues/derivatives thereof, whether viable or non-viable, are Class D - except where such devices are manufactured from or incorporate non-viable animal tissues or their derivatives that come in contact with intact skin only where they are in Class A.	**NOTE**: In some jurisdictions such products: - are considered to be outside the scope of medical devices regulations; - may be subject to different controls. It is likely the regulations controlling these devices will be the subject of future harmonization efforts.

15. All devices intended specifically to be used for disinfecting or sterilising medical devices are in Class B. All devices intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses are in Class C.	This rule does not apply to products that are intended to clean medical devices other than contact lenses by means of physical action e.g. washing machines. **NOTE**: In some jurisdictions solutions for use with contact lenses: - are considered to be outside the scope of medical devices regulations; - may be subject to different controls.
16. All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class C, unless they are implantable or long term invasive devices, in which case they are in Class D.	

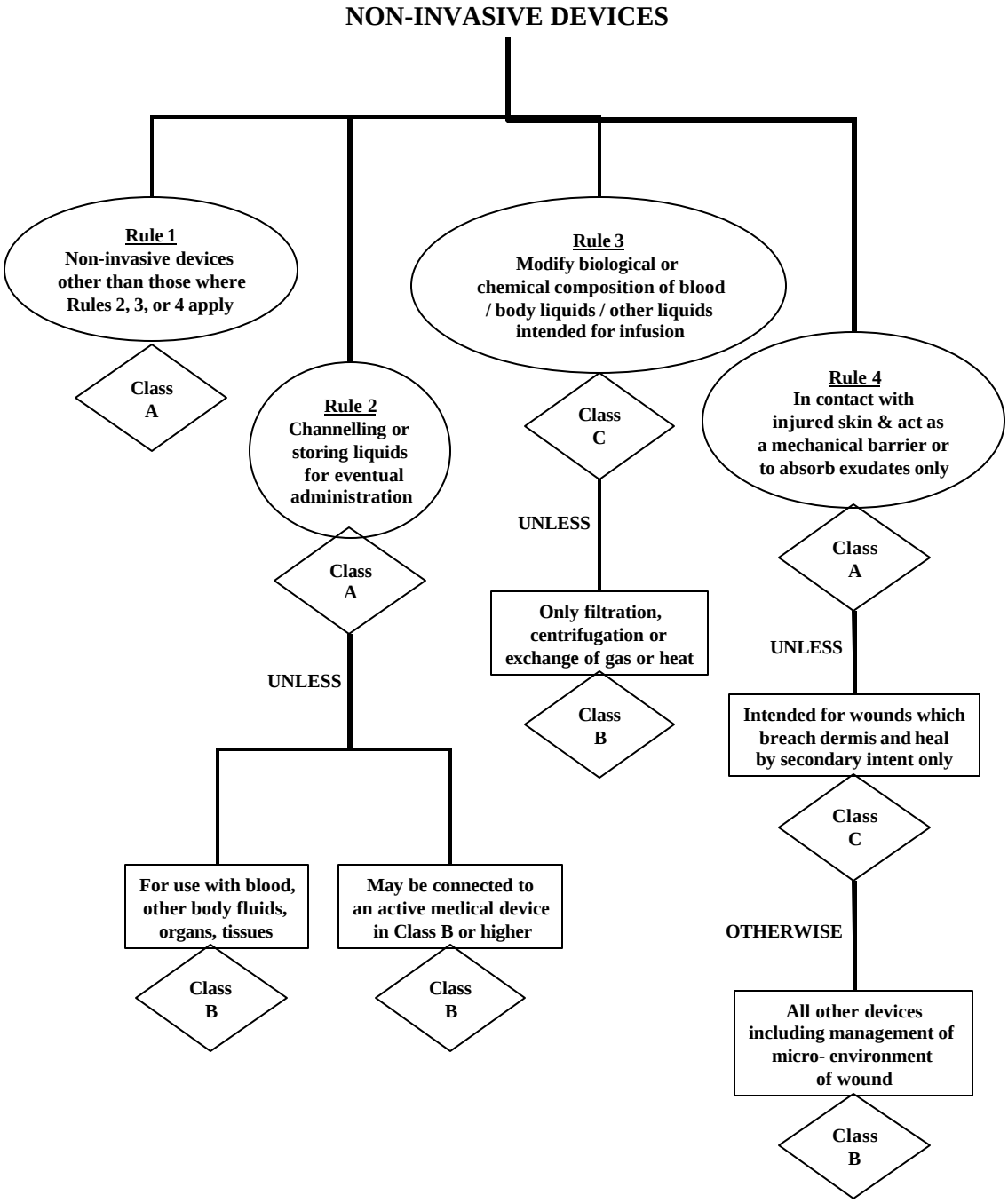
Decision trees illustrating how these rules should be used to classify specific devices are shown below.

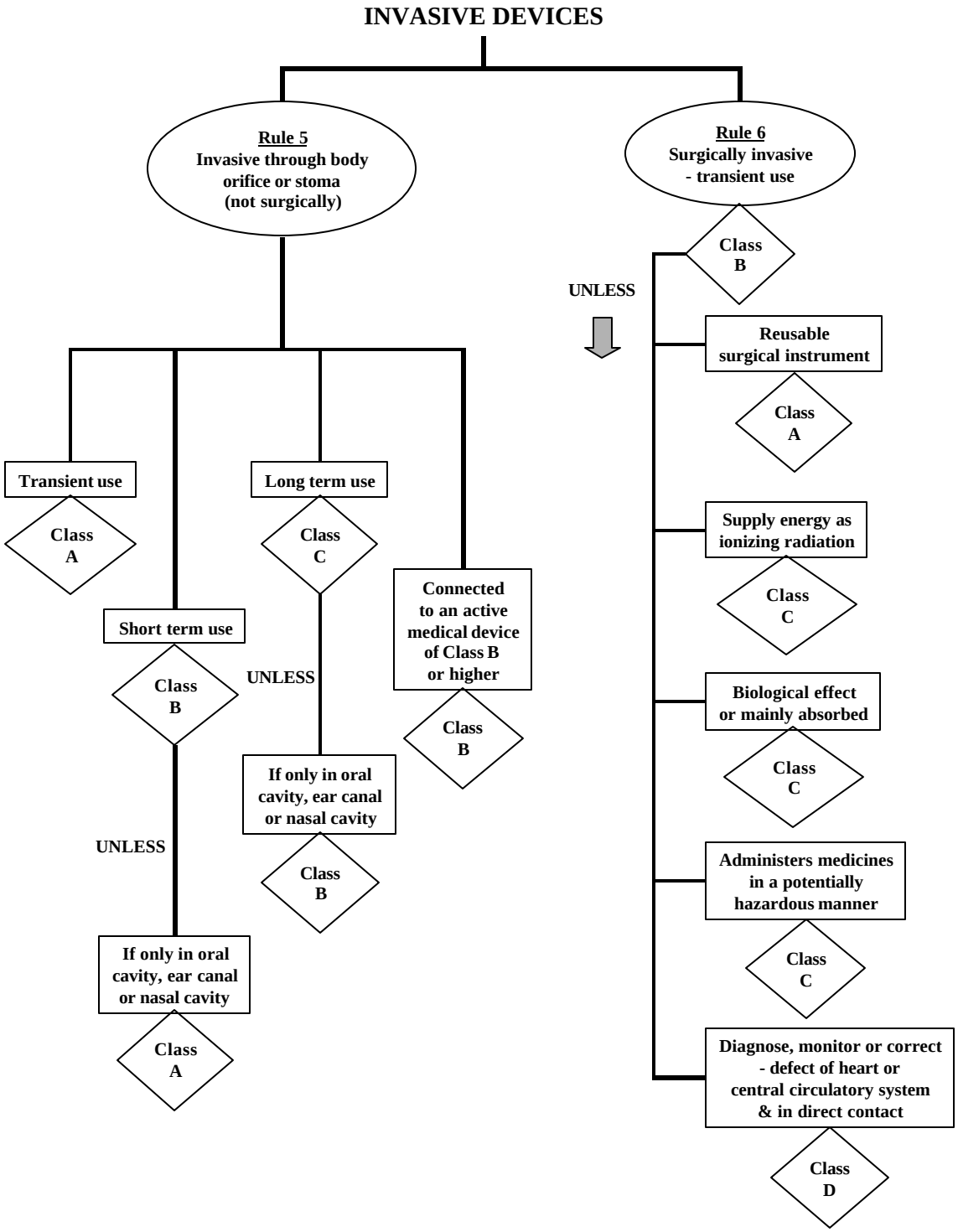
NOTE: these diagrams are for illustrative purposes only and the determination of risk class for a particular device should be made by referring to the rules themselves and not the decision trees.

NOTE: where a medical device has features that place it into more than one class, conformity assessment should be based on the highest class indicated.

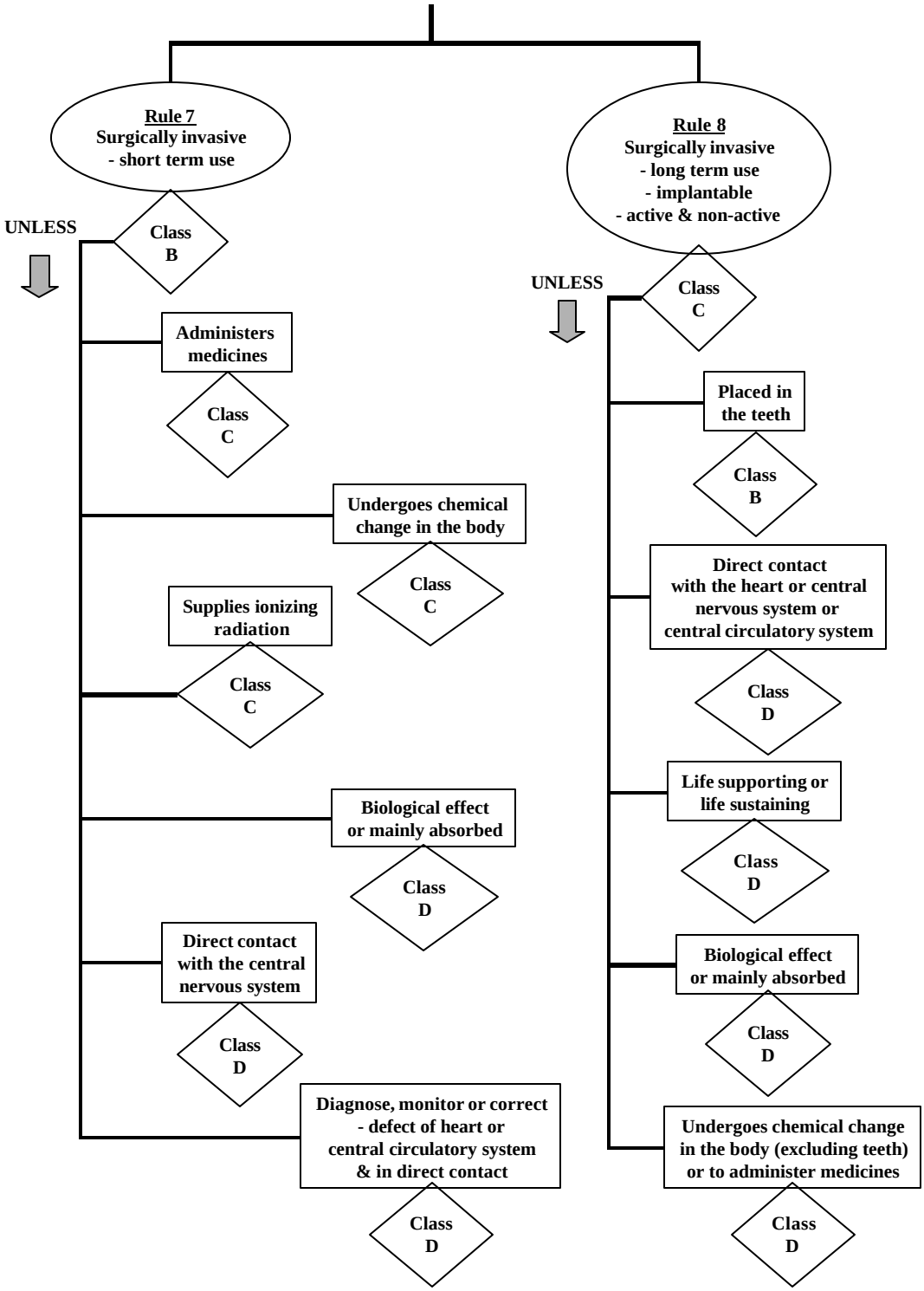
-

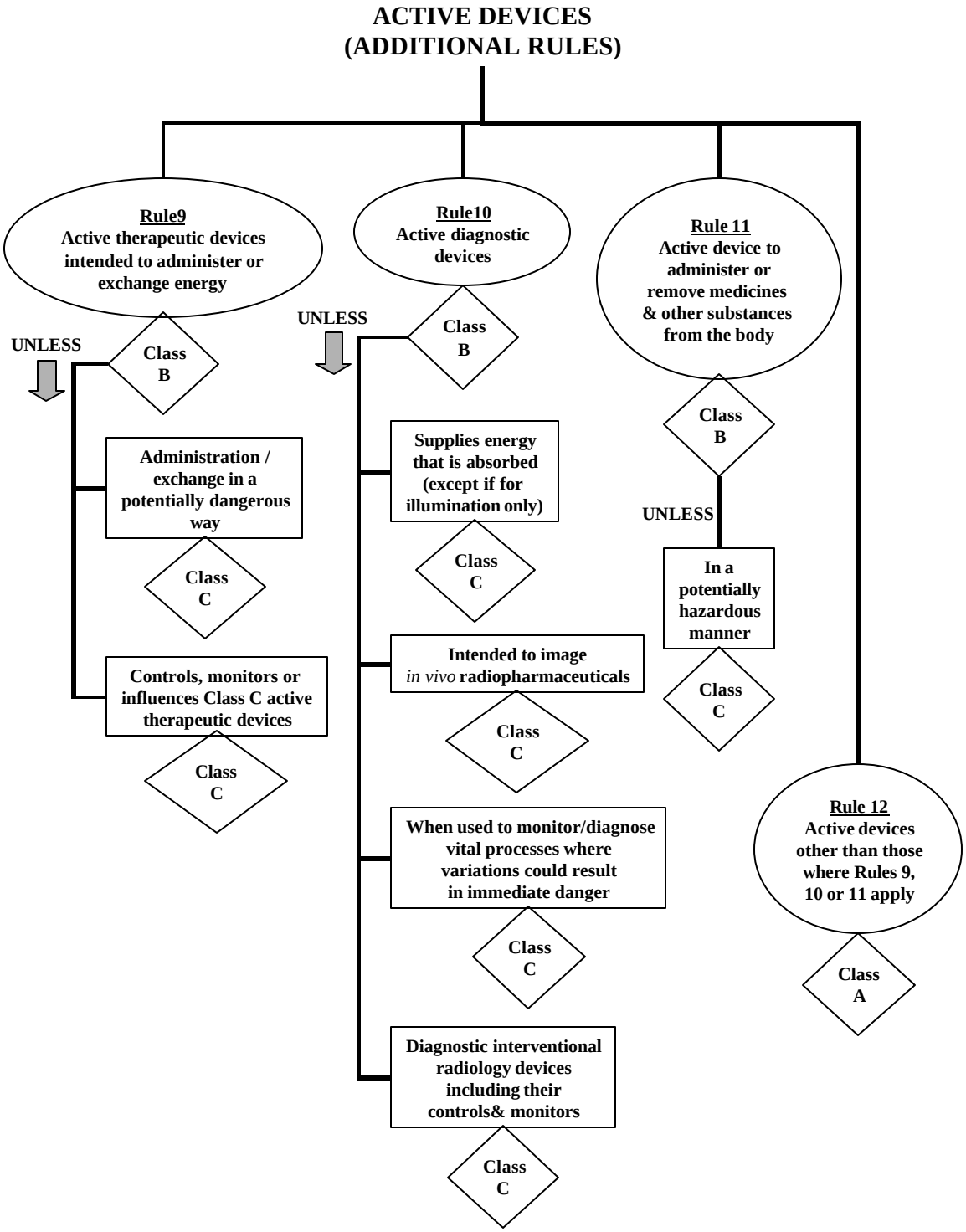
Figure 3: Decision Trees to demonstrate how these rules should be used to classify specific devices.

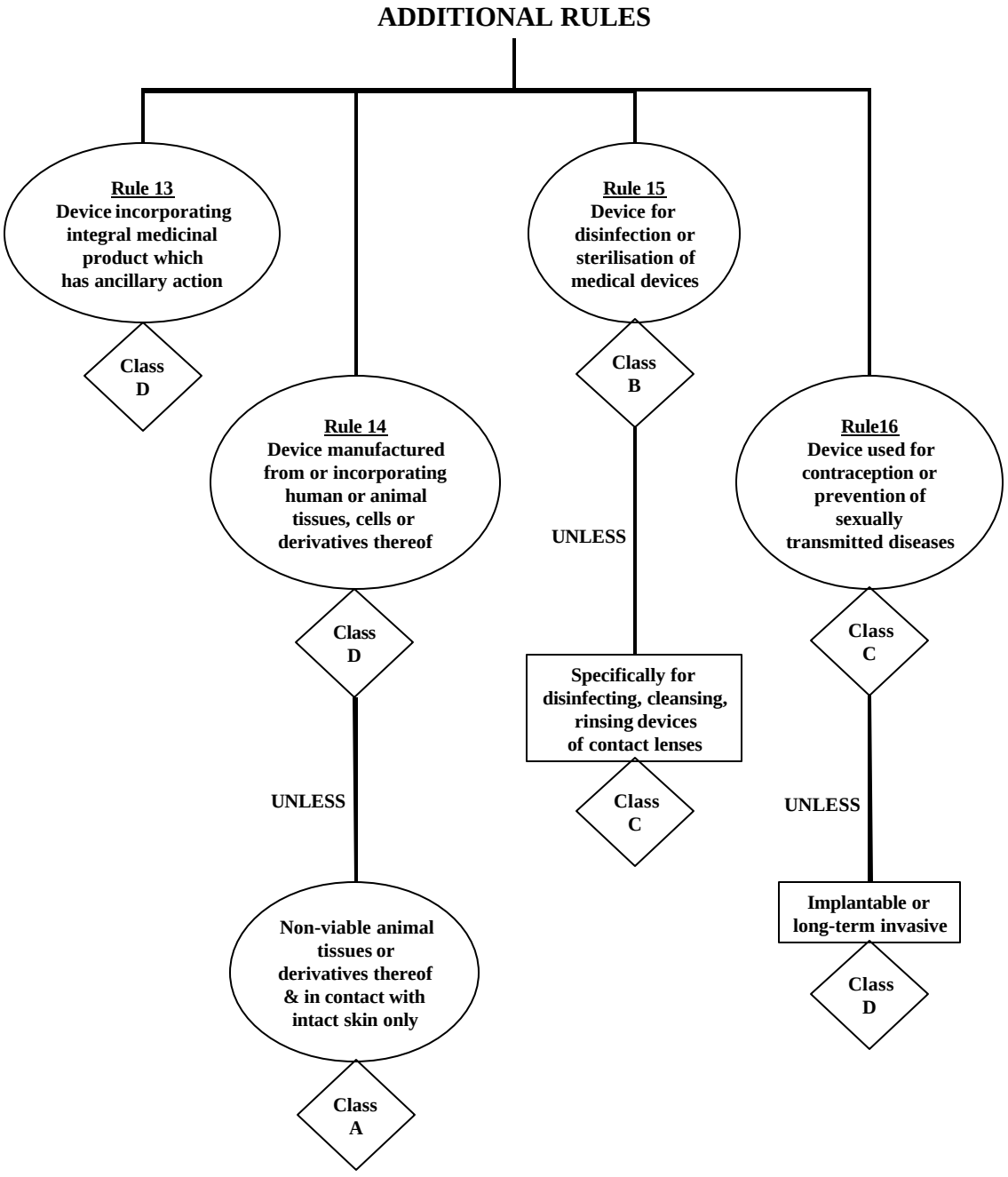



INVASIVE DEVICES
Rule 5
Invasive through body orifice or stoma (not surgically)
Rule 6
Surgically invasive - transient use
Class B
UNLESS
Reusable surgical instrument
Class A
Supply energy as ionizing radiation
Class C
Biological effect or mainly absorbed
Class C
Administers medicines in a potentially hazardous manner
Class C
Diagnose, monitor or correct - defect of heart or central circulatory system & in direct contact
Class D
Transient use
Class A
Short term use
Class B
UNLESS
If only in oral cavity, ear canal or nasal cavity
Class A
Long term use
Class C
UNLESS
If only in oral cavity, ear canal or nasal cavity
Class B
Connected to an active medical device of Class B or higher
Class B

INVASIVE DEVICES (continued)




ACTIVE DEVICES
(ADDITIONAL RULES)
Rule9
Active therapeutic devices intended to administer or exchange energy
UNLESS
Class B
Administration / exchange in a potentially dangerous way
Class C
Controls, monitors or influences Class C active therapeutic devices
Class C
Rule10
Active diagnostic devices
UNLESS
Class B
Supplies energy that is absorbed (except if for illumination only)
Class C
Intended to image in vivo radiopharmaceuticals
Class C
When used to monitor/diagnose vital processes where variations could result in immediate danger
Class C
Diagnostic interventional radiology devices including their controls& monitors
Class C
Rule 11
Active device to administer or remove medicines & other substances from the body
Class B
UNLESS
In a potentially hazardous manner
Class C
Rule 12
Active devices other than those where Rules 9, 10 or 11 apply
Class A


ADDITIONAL RULES
Rule 13
Device incorporating integral medicinal product which has ancillary action
Class D
Rule 14
Device manufactured from or incorporating human or animal tissues, cells or derivatives thereof
Class D
UNLESS
Non-viable animal tissues or derivatives thereof & in contact with intact skin only
Class A
Rule 15
Device for disinfection or sterilisation of medical devices
Class B
UNLESS
Specifically for disinfecting, cleansing, rinsing devices of contact lenses
Class C
Rule16
Device used for contraception or prevention of sexually transmitted diseases
Class C
UNLESS
Implantable or long-term invasive
Class D